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NOTICE OF ALLOWANCE AND FEE(S) DUE

28977 7590 08/17/2010

MORGAN, LEWIS & BOCKIUS LLP
1701 MARKET STREET
PHILADELPHIA, PA 19103-2921

EXAMINER

STIGELL, THEODORE J

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 08/17/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,116	09/08/2003	John P. Willis	101085-5007-01US	9687

TITLE OF INVENTION: INJECTION DEVICE

APPL.N. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	11/17/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS** FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

28977 7590 08/17/2010
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Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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nonprovisional	YES	\$755	\$300	\$0	\$1055	11/17/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
STIGELL, THEODORE J	3763	604-068000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB-122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB-47; Rev 03-02 or more recent) attached. Use of a **Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____
Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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MORGAN, LEWIS & BOCKIUS LLP 1701 MARKET STREET PHILADELPHIA, PA 19103-2921			STIGELL, THEODORE J	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 08/17/2010

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 488 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 488 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability**Application No.**

10/658,116

Applicant(s)

WILLIS ET AL.

Examiner

THEODORE J. STIGELL

Art Unit

3763

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/2/2010.
2. ☒ The allowed claim(s) is/are 52-65.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Theodore J Stigell/
Examiner, Art Unit 3763

DETAILED ACTION
EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with John Hemmer on 8/11/2010.

The application has been amended as follows:

In the Specification:

- Please replace the paragraph under the Cross-Reference to Related

Applications heading amended on 9/8/2003 with the following paragraph:

This application is a continuation of U.S. Patent Application Serial No. 09/755,906, filed January 5, 2001, now U.S. Patent No. 6,616,627, issued September 9, 2003, which claims priority under 35 USC §119(e)(1) to U.S. Patent Application Ser. No. 60/174,876, filed on January 7, 2000, the entire contents of which are hereby incorporated by reference.

- On line 22 of page 4 of the specification, please delete "housing".
- Please replace the paragraph beginning at page 5, line 24 of the specification as amended on 9/8/2003 with the following paragraph:

The syringe adaptor 200 has an outer vent sleeve 150, a sliding piston 100 having pressure relief holes 130, sleeve 110 (e.g., a fixed sleeve) having a groove 120

(e.g., an annular groove), and a drive piston 170 having grooves containing sealing devices 180 (e.g., o-rings) and a syringe interface 190 (e.g., a custom syringe interface) located at its distal end. The sliding piston 100 includes a proximal end toward the proximal end of the housing and a distal end toward the distal end of the housing. The sleeve 110 includes a proximal end toward the proximal end of the housing and a distal end toward the distal end of the housing.

In the Claims:

- Please cancel claims 36-51.
- Please add the following new claims 52-65.

52. (NEW) An injection device for fluid injection into a body comprising:

a housing having a proximal end and a distal end, the housing having an opening proximate the distal end, the opening configured to deliver a fluid;

a fluid chamber disposed inside the housing and configured to contain the fluid;

a propellant chamber disposed inside the housing and spaced from the distal end of the housing;

a sleeve having a proximal end and a distal end, the sleeve disposed inside the housing between the distal end of the housing and the propellant chamber, the sleeve having a first cavity in fluid communication with the propellant chamber, and having an opening between the proximal end of the sleeve and the distal end of the sleeve; and

a piston mounted on the sleeve and having a proximal end and a distal end and having an opening between the proximal end of the piston and the distal end of the

piston, the piston being coupled to the sleeve and having a second cavity, the piston being movable with respect to the sleeve from a first position to a second position,

wherein, during use, a fluid is released from the propellant chamber causing the piston to slide over a surface of the sleeve from the first position to the second position, movement of the piston causing the fluid in the fluid chamber to be ejected through the housing opening, and

wherein as the piston slides over the sleeve, the opening of the piston aligns with the opening of sleeve such that at least some of the fluid from the propellant chamber travels through the aligned openings of the sleeve and piston.

53. (NEW) The injection device of claim 52, wherein the opening of the piston is configured to assist in controlling pressure of the fluid being ejected through the housing opening.

54. (NEW) The injection device of claim 52, wherein the sleeve further includes a groove, the opening of the sleeve disposed in the groove.

55. (NEW) The injection device of claim 54, wherein the groove is annular.

56. (NEW) The injection device of claim 52, wherein the opening of the piston includes a plurality of axially spaced openings that are each alignable with the opening of the sleeve.

57. (NEW) The injection device of claim 52, wherein the housing is comprised of a plurality of housing components.

58. (NEW) The injection device of claim 52, wherein the fluid from the propellant chamber is a gas that urges the piston from the first position to the second position.

59. (NEW) The injection device of claim 52, wherein the second cavity is in fluid communication with an exterior of the housing when the piston and sleeve openings are aligned.
60. (NEW) The injection device of claim 52, wherein the fluid from the propellant chamber is released from a propellant disposed within the propellant chamber.
61. (NEW) The injection device of claim 60, further comprising:
- a button coupled to the housing proximate the proximal end of the housing;
 - a battery disposed inside the housing and adjacent to the button;
 - electrical leads in electrical communication with the battery; and
 - a wire in electrical communication with the electrical leads, the wire configured to trigger the propellant.
62. (NEW) The injection device of claim 60, wherein the propellant includes a chemical pyrotechnic material.
63. (NEW) The injection device of claim 52, wherein the device is a needleless injection device.
64. (NEW) The injection device of claim 52, further comprising:
- a filter disposed between the propellant chamber and the first cavity.
65. (NEW) The injection device of claim 52, wherein the housing includes a vent, at least some of the fluid from the propellant chamber exiting through the vent after traveling through the openings of the sleeve and the piston.

The following is an examiner's statement of reasons for allowance: The prior art made of record did not disclose or render obvious an injection device comprising the combination of limitations recited in claim 52. In regard to McKinnon '413, there is no disclosure of at least a piston mounted on a sleeve wherein the piston is movable over a surface of a sleeve and further wherein the piston and sleeve include an opening between their respective ends. There is no teaching reference to include these limitations in the McKinnon '413 device and furthermore such limitations would appear to destroy the McKinnon '413 device as the piston (90) is movable inside the sleeve and not over it. In regard to Willis '455, there is no disclosure of a sleeve and a piston with an opening between their respective ends wherein the openings are alignable with each other during movement of the piston over the sleeve so that fluid from the propellant chamber can travel therethrough. Willis discloses a piston (10) slidable over a sleeve (element defining 11) but does not disclose an opening in either the sleeve or the piston between their ends. Furthermore, there is no teaching reference to modify the device of Willis '455 with these limitations.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763